Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

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PMPRB NEWSletter

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Notice to Readers

Reminders

- The PMPRB no longer issues e-bulletins. To be notified of new announcements, publications, and other initiatives, please follow us on Twitter or subscribe to our RSS feeds.

Message from the Chairperson on the 30th anniversary of the PMPRB

On December 7, 1987, the Patented Medicine Prices Review Board was established under the Patent Act with a mandate to protect consumers by ensuring that prices of patented medicines are not excessive. Thirty years later, the PMPRB continues to carry out its mandate by regulating the price of patented drugs at the factory gate level and by keeping a vigilant eye on pricing trends and industry research and development (R&D).

Canada

Since 1993, $195 million in excess revenues have been recovered by the PMPRB through Voluntary Compliance Undertakings and Board Orders. In addition to reporting annually on pharmaceutical pricing trends and R&D, the PMPRB contributes to Canada's understanding of drug usage through the National Prescription Drug Utilization Information System (NPDUIS) initiative, generating comprehensive, accurate information to help guide decision making and support the continued sustainability of our pharmaceutical system.

Since its inception, the PMPRB has sought to adapt its regulatory and reporting function in response to the evolving nature of the pharmaceutical sector. With the population aging and using more prescription drugs—and sometimes more expensive types of drugs—Canada's spending on pharmaceuticals is expected to increase significantly in the years to come. Medical advancements have introduced many innovative new drugs to the Canadian marketplace to improve existing treatments and to treat conditions that previously had no pharmaceutical therapy. These include high-cost orphan drugs, biologics and oncology drugs.

In December 2015, the PMPRB published its 2015-2018 Strategic Plan, an important turning point in the organization's history as it looks to reform how it carries out its consumer protection mandate in light of recent significant changes in its operating environment. Budget 2017 proposed a significant increase in funding for the PMPRB, as part of the Government's commitment to making prescription drugs more accessible for Canadians. We take this as a vote of confidence in our potential to play a more meaningful and relevant role in the sustainability of Canada's health system.

On December 2, 2017, Health Canada published proposed amendments to the Patented Medicines Regulations in Part I of the Canada Gazette. The PMPRB welcomes the Minister of Health's action to strengthen and modernize its pricing framework to reduce the cost of prescription drugs. If passed, these reforms would provide the PMPRB tools that are in line with international best practices and better position us to protect Canadian consumers from excessive prices in today's pharmaceutical marketplace. Now that the consultation period for proposed amendments has come to a close, we look forward to working with all our stakeholders as the PMPRB transitions toward a modern, risk-based approach to drug price regulation.

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New Year's message from the Executive Director

As most of our readership will know, 2018 is the third and final year of the PMPRB's 2015-2018 Strategic Plan. While we've made great strides over the past three years in advancing the very ambitious objectives we set for ourselves back in 2015, the window is closing on our ability to deliver on the most important objective of all – modernizing our regulatory framework - within the timelines envisaged in that document. Last year, our Minister committed to having new regulations up and running by January 2019, such that these timelines are no longer merely notional. With less than a year to go to meet that deadline, it is crunch time at the PMPRB, as reflected in both the brevity and belatedness of this new year's message.

With the release of Health Canada's white paper on proposed amendments to the Patented Medicines Regulations in May of last year, and the subsequent gazetting of those amendments and publication of the PMPRB's scoping paper in December, our regulatory and reporting activities have come under increasing scrutiny. As a result, there is likely no need for me to offer up my standard recap of the past year. Suffice to say that 2017 was a year of firsts on a number of fronts. Not only did it see a sweeping set of proposed regulatory reforms – the first such set of amendments in over twenty years – it also featured the Board's first decision on the merits in an excessive pricing hearing since 2012, and a record breaking one-time VCU payment of $31 million.

As for what lies ahead in 2018, while we will continue to provide analytical support to our Health Canada colleagues as they push to finalize the regulatory amendments, our focus will be consulting with our stakeholders on the details of the risk-based regulatory framework described in our December scoping paper. Building on the dialogue which took place in at our annual outreach session with patentees in January, we intend to publish a draft set of proposed new Guidelines for comment in the spring and strike technical working groups on discrete components of that framework through the summer and early fall, with a view to finalizing the document by December. We recognize that this is an aggressive timetable given the very technical nature of the subject matter and that success will depend on constructive engagement with all of our stakeholders. While some may disagree with aspects of these changes or their underlying policy rational, we are hopeful that stakeholders of all stripes will recognize that it is in everyone's interests to work towards the best, most technically sound document that time allows.

Finally, although word of his appointment has already been communicated publicly through news releases issued by both Health Canada and our own Secretariat, it is no less a pleasure for me to draw attention here to the fact of Dr. Mitchell Levine's recent confirmation as Chairperson of our Board, a position he has occupied on an acting basis for the better part of the past year. Dr. Levine's appointment will provide much needed continuity for the PMPRB during a time of unprecedented transformation and change. Speaking on behalf of all of PMPRB staff, we look very much forward to continuing the important work of delivering on the Government's commitment to improve the accessibility of prescription drugs in Canada under Dr. Levine's very capable and resolute leadership.

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New release: 2016 PMPRB Annual Report

The Honourable Ginette Petitpas Taylor, Federal Minister of Health, tabled the 2016 Annual Report of the PMPRB with the Clerks of the House of Commons and the Senate on October 26, 2017.

The 2016 Annual Report sets out detailed information on the PMPRB's regulatory activities; patentees' compliance with the Board's pricing guidelines; sales and price trends of patented drugs in Canada, including international price comparisons, trends in all drug expenditures, and spending on pharmaceutical research and development.

The 2016 Annual Report of the PMPRB is available on the PMPRB website.

Highlights

- Canadian patented drug prices were fourth-highest among the seven countries Canada compares itself to under PMPRB regulations (the "PMPRB7"), lower than Switzerland, Germany and the United States but higher than the UK, France, Sweden and Italy.
- Sales of patented drug products increased in 2016 by 2.6% to $15.5 billion.
- Drugs that treat blood and blood forming organs had the greatest impact on sales growth in 2016. This class of drugs accounted for 5.7% of sales in 2016, an increase of 15.4% from the previous year.
- 1,435 patented drug products were reported to the PMPRB in 2016.

- The R&D-to-sales ratios of pharmaceutical patentees in Canada remained unchanged from 2015 at 4.4%, as compared to the 22% average in the PMPRB7.
- There were 101 ongoing investigations into possible excessive patented drug pricing as of March 31, 2017.
- Enforcement action taken by the PMPRB in 2016 resulted in over $5 million in excess revenues paid back by pharmaceutical patentees to the Government of Canada, in addition to price reductions.
- Between 2006 and 2016 the number of medicines in Canada with an annual per beneficiary cost of at least $10,000 increased by over 200% and now accounts for 40% of patented drug sales as compared to 7.6% in 2006.

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Update on Guideline reform

On December 12, 2017, the PMPRB released a scoping paper explaining how it envisages operationalizing Health Canada's proposed amendments to the Patented Medicines Regulations. This document, which is intended to be read in conjunction with the proposed amendments and the accompanying Regulatory Impact Analysis Statement, will serve as a catalyst for a more informed, focused and productive consultation on framework modernization.

The future framework envisioned by the PMPRB aspires towards bright line tests that yield ceiling prices that are reasonable and foreseeable to patentees.

While the details of the framework remain to be worked out through consultation, its basic structure can be described as a risk based approach to pricing review that is broken down into five main parts:

- Interim international price reference test;
- Screening;
- High priority drugs;
- Medium and low priority drugs; and
- Re-benching

Stay tuned to the PMPRB's website and Newsletter for more information on next steps in our consultation process on Guideline reform.

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PMPRB Hearing Panel issues decision in Soliris case

On September 27, 2017, a Patented Medicine Prices Review Board Hearing Panel issued its decision relating to the medicine Soliris, manufactured and marketed in Canada by Alexion Pharmaceuticals Inc. The Panel found that the price of Soliris (eculizumab) 10 mg/mL was and is excessive under sections 83 and 85 of the Patent Act. The Panel ordered Alexion to pay to Her Majesty in right of Canada an amount of excess revenue calculated in accordance with Schedule A to the decision. The Hearing Panel also ordered Alexion to lower the list price of Soliris in Canada to no higher than the lowest price in the comparator countries set out in the Patented Medicines Regulations.

On October 20, 2017, Alexion Pharmaceuticals Inc. sought judicial review of the decision before the Federal Court.

On November 8, 2017, the Panel ordered Alexion to pay back excess revenues to Her Majesty in right of Canada in the amount of $4,245,329.60 on or before December 8, 2017.

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Federal Court of Appeal reiterates constitutional validity of the PMPRB

In a decision dated December 7, 2017 Canada's Federal Court of Appeal (2017 FCA 241) dismissed an appeal of a Federal Court decision striking an application for judicial review seeking a declaration that the excessive price provisions of the Patent Act were unconstitutional.

The judicial review application was originally brought in September 2015 by Alexion Pharmaceuticals Inc., which sells the patented drug Soliris whose price was, at the time, the subject of a hearing before the Board. The Attorney General of Canada moved to strike the application on the grounds that it was "bereft of any chance of success" in view of the Federal Court of Appeal's decision in the Sandoz case (2015 FCA 249) that confirmed the constitutionality of the excessive price provisions of the Patent Act. The motion to strike was granted by Prothonotary Aalto based on stare decisis (2016 FC 716) and later upheld by Justice Simpson (2017 FC 22). Alexion then appealed to the Federal Court of Appeal alleging that the Sandoz decision was not binding authority.

The Federal Court of Appeal upheld the decision of the Federal Court. In addition, on its own motion, the Court addressed the issue of whether it was appropriate for Alexion to launch an application for judicial review before putting the arguments before the Board. In this regard, the Court held that Alexion should not have bypassed the Board and that "by bypassing the Board, the application has undermined its position as the first instance forum for decisions of fact and of law within its mandate, and deprived the reviewing court of the Board's insights on the purpose and operation of the challenged provisions." While the Court would have dismissed Alexion's appeal on this ground alone, it proceeded to address the issues raised in the appeal in the interest of judicial economy.

Alexion has sought leave to appeal to the Supreme Court of Canada.

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PMPRB bids farewell to Elaine McGillivray

It is with a heavy heart and great fondness that we bid farewell to Elaine McGillivray Executive Assistant Board Secretariat, Communications and Strategic Planning, who retired in October 2017, after 30 years with the PMPRB. Elaine was the first employee hired by the PMPRB. She played a vital role in shaping the Board Secretariat activities and was also the driving force behind many of the PMPRB's social functions and charitable activities. We all miss Elaine and wish her nothing but the best.

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2018 CPI-Based Price-Adjustment Factors for Patented Drug Products

The following table provides the CPI-Based Price-Adjustment factors for 2018. These factors were based on the actual rate of CPI inflation of 2.0% in 2014, 1.1% in 2015 and 1.4% in 2016.

CPI-Based Price-Adjustment factors for 2018			
Benchmark Year	2015	2016	2017
Price-Adjustment Factor	1.045	1.026	1.014

Based on these factors, one can derive: (1) a maximum allowable cumulative price increase between 2015 and 2018 of 4.5% for patented drug products with Canadian sales in 2015; (2) a maximum allowable cumulative price increase between 2016 and 2018 of 2.6% for patented drug products with Canadian sales in 2016; and (3) a maximum allowable cumulative price increase between 2017 and 2018 of 1.4% for patented drug products with Canadian sales in 2017.

The year-over-year price increase cap for the 12-month period ending December 2018 is 2.1% (=1.5 x Actual Inflation in 2016).

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NPDUIS update: Engagement activities

NPDUIS Advisory Committee

The NPDUIS group continues to engage with stakeholders to exchange information and share the results of their analyses. In conjunction with the publication of major studies, presentations of the findings are offered to key stakeholders including policy makers, academics and consumer and industry groups.

On October 4, the NPDUIS group hosted its annual face-to-face meeting with its Advisory Committee. The Advisory Committee guides the analytical direction of the NPDUIS initiative and is composed of public drug plan representatives and participants from Health Canada, the Canadian Institute for Health Information, the Canadian Agency for Drugs and Technologies in Health, the Ministère de la Santé et des Services sociaux (MSSS) du Québec and the pan-Canadian Pharmaceutical Alliance (pCPA) Office. NPDUIS staff presented the preliminary results of a number of new studies and explored future analytical priorities.

For more information on future research topics and publications, see the NPDUIS Research Agenda on the PMPRB website and follow the PMPRB on Twitter.

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New and upcoming publications

New Release: Formularies in Canada - Part 1

On October 11, the PMPRB released the first report in a new three-part series that compares drug coverage across provincial and federal public drug plans. The information contained in these reports will inform the dialogue on improving the affordability and accessibility of necessary prescription drugs, including exploring the need for a national formulary.

Alignment among Public Formularies in Canada - Part 1: General Overview

This report compares the public plan listings for 729 selected drugs, accounting for 82% of the total public drug costs in 2015. It also provides a detailed examination of the degree of overlap for specific market segments including generic drugs and branded products, high-cost drugs, and a specified list of drugs identified as essential for primary health care in Canada.

The analysis found a significant overlap in the drugs covered by Canadian public drug plans. Individual formularies listed an average of 79% of the selected drugs. When costs were factored in, the average listing rate increased to 95%, indicating that the drugs not covered by plans only represented an average of 5% of costs. Individual plans listed almost all the list of medicines essential for primary care, with an average listing rate of 92%. In general, generic drugs had higher listing rates than branded products and the variation among public plans was greatest for high-cost drugs.

The next two parts of the series will focus on newer drugs reviewed through the Common Drug Review (CDR) and oncology drugs assessed through the pan-Canadian Oncology Drug Review (pCODR) process.

Generics360, 2016

The latest issue of Generics360 was published on February 6, 2018. This series explores recent trends in domestic and international generic drug pricing, sales and utilization. The results inform policy decision makers, academics and the pharmaceutical industry in Canada.

Generics360: Generic Drugs in Canada, 2016

In addition to the regular highlights, such as price trends in the Canadian market and international price comparisons, the current issue features several new analyses. These include a review of generic spending in Canada relative to the brand market and the Organisation for Economic Co-operation and Development (OECD) countries; a market segment analysis of drugs subject to pan-Canadian Pharmaceutical Alliance (pCPA) policies; and an analysis of the cost impact of Canadian and international generic price differentials for public plans.

The report finds that Canada has a strong generics market with the third highest rate of generic drug use among OECD countries and the second highest per capita spending on generics in 2016.

Despite the strength of the Canadian generic market and the implementation of numerous provincial/territorial policies aimed at reducing prices, Canada still pays some of the highest prices for generic drugs. The impact of this price differential translates into nearly half a billion dollars in public plan drug costs.

Coming soon in 2018:

Meds Entry Watch, 2nd Edition

The new drugs launched in Canadian and international markets are featured in this annual NPDUIS publication. This is the second edition in the series and provides up-to-date information on drugs launched in 2015 as well as preliminary listing and pricing information for drugs launched in 2016.

The analysis explores the availability and sales of new drugs in Canada and the PMPRB7; measures international uptake and price differentials; and reports on the level of therapeutic improvement, health technology assessments, price negotiation status and reimbursement decisions for new drugs available in Canada.

CompassRx, 4th edition

This annual NPDUIS report contains valuable information on the major factors driving prescription drug spending in public drug plans in Canada. It is a key resource for policy makers and researchers – highlighting factors relevant for understanding the sources of current cost pressures and potential future trends

Potential Savings from Biosimilars in Canada

This analysis targets top-selling biologic biosimilars that are currently on the market or are expected to enter it within the next few years. The analysis will contribute important information to the discussion on the approval, pricing and reimbursement of biosimilar drugs.

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Voluntary Compliance Undertakings

A Voluntary Compliance Undertaking (VCU) is a written undertaking by a patentee to adjust its price to conform to the Board's Guidelines. Under the Guidelines, patentees are given an opportunity to submit a VCU when the price set by the patentee for a patented drug product sold in Canada appears to have exceeded the Guidelines. A VCU can also be submitted by a patentee after a Notice of Hearing is issued. VCUs represent a compromise between the PMPRB and the patentee as a result of negotiations between the parties in view of the specific facts and underlying context of a particular case. As such, VCUs are not intended to have precedential value.

In the first two months of 2018, two (2) VCUs were accepted for the patented medicines Repatha (Amgen Canada Inc.); and DuoTrav PQ.

Repatha

Repatha (evolocumab) 140 mg/syringe (Repatha) is indicated as an adjunct to diet and maximally tolerated statin therapy in adult patients with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD) who require additional lowering of low density lipoprotein cholesterol (LDL-C).

On January 10, 2018, the Acting Chairperson of the Board approved a VCU by Amgen Canada Inc. ("Amgen") regarding the price of Repatha. Amgen agreed to reduce the price of Repatha and to ensure that its price through 2019 will be set by the lower of the CPI-Adjustment Methodology and

the lowest international price of the seven countries set out in the Patented Medicines Regulations. Amgen will also repay cumulative excess revenues as of December 31, 2017 by making a payment to the Receiver General of Canada, and ensure that the price of Repatha remains within the thresholds set out in the Guidelines in all future periods during which it is under the PMPRB's jurisdiction.

DuoTrav PQ

DuoTrav PQ is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to beta-blockers, prostaglandins, or other IOP lowering agents.

On January 16, 2018, the Acting Chairperson of the Board approved a VCU by Novartis Pharmaceuticals Canada Inc. ("Novartis") regarding the price of DuoTrav PQ. Novartis agreed to reduce the price of DuoTrav PQ and to repay cumulative excess revenues of $275,000 by making a payment to the Receiver General of Canada, as well as to ensure that the price of DuoTrav PQ remains within the thresholds set out in the Guidelines in all future periods during which it is under the PMPRB's jurisdiction.

In the third quarter of 2017, nine (9) VCUs were accepted for the patented medicines Puregon and Zerbaxa (Merck Canada Inc.); Tridural (Paladin Laboratories Inc.); Cysview (BioSyent Pharma Inc); Effient and Adcirca (Eli Lilly Canada Inc.); Cyramza (Eli Lilly Canada Inc.); Truvada and Genvoya (Gilead Sciences Inc.); Bridion (Merck Canada Inc.); Zepatier (Merck Canada Inc.); and Humira (AbbVie Inc.).

Puregon and Zerbaxa

Puregon (follitropin beta) is indicated in females for the development of multiple follicles in ovulatory patients participating in an Assisted Reproduction Technology program. Zerbaxa is indicated in adult patients for the treatment of complicated urinary tract infections, including pyelonephritis, caused by Gram-negative microorganisms.

On July 28, 2017, the Acting Chairperson of the Board approved a VCU submitted by Merck Canada Inc. (Merck) regarding the price of Puregon and the no longer patented medicine Zerbaxa. Under the terms of the VCU, Merck agreed to reduce the price of Puregon and to repay cumulative excess revenues of $750,000 by making a payment to the Receiver General of Canada.

Merck further agreed to provide notice to the PMPRB in the event that other patents pertaining to Zerbaxa are issued in any future periods and will ensure that the price of both drugs subject to the VCU remain within the thresholds set out in the Guidelines in all future periods during which they are under the PMPRB's jurisdiction.

Tridural

Tridural (tramadol hydrochloride) is indicated for the management of moderate to moderately severe pain in adults who require treatment for several days or more.

On August 1, 2017, the Acting Chairperson of the Board approved a VCU submitted by Paladin Labatories Inc. (Paladin) regarding the price of Tridural. Under the terms of the VCU, Paladin agreed to reduce the price of Tridural.

Paladin will also ensure that the price of Tridural remains within the thresholds set out in the Guidelines in all future periods during which it is under the PMPRB's jurisdiction.

Cysview

Cysview (hexaminolevulinate hydrochloride) is an optical imaging agent indicated for use in the cryptoscopic detection of non-muscle invasive papillary cancer of the bladder among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy.

On September 12, 2017, the Acting Chairperson of the Board approved a VCU submitted by BioSyent Pharma Inc. (BioSyent) regarding the price of Cysview. Under the terms of the VCU, BioSyent agreed to reduce the price of Cysview and to repay cumulative excess revenues of $4,433.13 by making a payment to the Receiver General of Canada.

BioSyent will also ensure that the price of Cysview remains within the thresholds set out in the Guidelines in all future periods during which it is under the PMPRB's jurisdiction.

Effient and Adcirca

Effient, co-administered with acetylsalicylic acide, is indicated for the early and long-term secondary prevention of atherothrombotic events in patients with acute coronary syndrome. Adcirca is indicated for the treatment of idiopathic ("primary") pulmonary arterial hypertension.

On September 12, 2017, the Acting Chairperson of the Board approved a VCU submitted by Eli Lilly Canada Inc. (Eli Lilly) regarding the prices of Effient and Adcirca. Under the terms of the VCU, Eli Lilly agreed to reduce the prices of Effient and Adcirca and to offset cumulative excess revenues of $449,355.32 by further reducing the 2017 price for both Effient and Adcirca below their respective 2016 National Non-Excessive Average Prices (N-NEAPs).

Eli Lilly will also ensure that the prices of both drugs subject to the VCU remain within the thresholds set out in the Guidelines in all future periods during which they are under the PMPRB's jurisdiction.

Cyramza

Cyramza is indicated for the treatment of patients with advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma.

On September 12, 2017, the Acting Chairperson of the Board approved a VCU submitted by Eli Lilly Canada Inc. (Eli Lilly) regarding the price of Cyramza. Under the terms of the VCU, Eli Lilly agreed to reduce the price of Cyramza and to offset cumulative excess revenues of $335,531.56 by further reducing the 2017 price below its 2016 N-NEAP.

Eli Lilly will also ensure that the prices of the drugs subject to the VCU remain within the thresholds set out in the Guidelines in all future periods during they are under the PMPRB's jurisdiction.

Truvada and Genvoya

Truvada, used with other antiretroviral agents, is indicated to treat human immunodeficiency virus type 1 (HIV-1) infection in adults or to reduce the risk of HIV-1 infection in adults at high risk. Genvoya is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age or older.

On October 16, 2017, the Acting Chairperson of the Board approved a VCU submitted by Gilead Sciences Inc. (Gilead) regarding the prices of Truvada and Genvoya. Under the terms of the VCU, Gilead agreed to reduce the prices of 2016 Truvada and Genvoya and agreed to repay cumulative excess revenues of $479,733.49 by making a payment to the Receiver General of Canada.

Gilead will also ensure that the prices of both drugs subject to the VCU remain within the thresholds set out in the Guidelines in all future periods during which they are under the PMPRB's jurisdiction.

Bridion

Bridion (sugammadex) is indicated for the reversal of moderate or deep neuromuscular blockade (NMB) induced by rocuronium or vecuronium.

On November 7, 2017, the Acting Chairperson of the Board approved a VCU submitted by Merck Canada Inc. (Merck) regarding the prices of Bridion. Under the terms of the VCU, Merck agreed to reduce the price of Bridion in 2017 and take no price increase in 2018.

Merck will also ensure that the price of Bridion remains within the thresholds set out in the Guidelines in all future periods during which it is under the PMPRB's jurisdiction.

Zepatier

Zepatier (elbasvir/grazoprevir) is indicated for the treatment of chronic hepatitis C (CHC) genotypes 1, 3, or 4 infection in adults with or without ribavirin, or with sofosbuvir.

On November 7, 2017, the Acting Chairperson of the Board approved a VCU submitted by Merck Canada Inc. (Merck) regarding the prices of Zepatier. Under the terms of the VCU, Merck agreed to lower the price of Zepatier and to repay cumulative excess revenues of $427,557.00 by making a payment to the Receiver General of Canada.

Merck will also ensure that the price of Zepatier remains within the thresholds set out in the Guidelines in all future periods during which it is under the PMPRB's jurisdiction.

Humira

Humira (adalimumab) is a tumor necrosis factor (TNF) blocker that reduces the effects of substances in the body that cause inflammation. Humira is used to reduce the signs and symptoms of moderately to severely active rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis, and a chronic skin condition called hidradenitis suppurativa. It is also used to reduce the signs and symptoms of moderately to severely active Crohn's disease or moderately to severely active ulcerative colitis after other drugs have been tried without successful treatment of symptoms.

On December 12, 2017, the Acting Chairperson of the Board approved a VCU submitted by AbbVie Inc. (AbbVie) regarding the price of Humira. Under the terms of the VCU, AbbVie agreed not to increase the price of Humira in any market through 2019 and to repay any excess revenues generated during this period.

AbbVie will also ensure that the price of Humira remains within the thresholds set out in the Guidelines in all future periods during which it is under the PMPRB's jurisdiction.

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Summary of the Board's September 2017 and January 2018 meetings

The Board held its first meeting of 2018 on January 16.

In both the January 2018 and September 2017 meetings, the Acting Chairperson provided an update on Board operations. Board Members were also debriefed on the latest developments with respect to regulatory framework modernization and on NPDUIS activities.

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